were noted. In addition the 2011 South African Census was reviewed. **RESULTS:** The 2011 census revealed, of 11 official languages, English is the most common 'everyday' language in business, politics and the media. However, it's not the most common language spoken at home. This inconsistency causes translation issues for the following reasons: (1) English names are commonly used for diseases and drugs, as these are referred to in 'home' languages with varying localised terms/descriptions (2) There is not the same broad vocabulary in the 'home' languages, due to the prevalence of English outside of the home, so descriptions are often used to reflect the source wording (3) Attitudes towards biomedicine can be subject to cultural differences in South Africa so certain concepts have to be localised and may appear to differ significantly from the source (4) 'Home' languages are not often written so have evolved erratically, with different linguists having different opinions on spelling and grammar **CONCLUSIONS:** This distinction between the 'everyday' language used in work, education, etc. and the 'home' languages causes difficulties with linguistic validation for South Africa. Linguists disagree on the general use of the languages which seems to be constantly changing. However, while the translation issues are multiple and varied the linguistic validation process appears to provide the resolutions, where all source wording is translated, reviewed, questioned and discussed in order to find a conceptual equivalent rather than a literal translation.

PRM114

RECOMMENDATIONS FOR THE LINGUISTIC VALIDATION OF PEDIATRIC CLINICAL OUTCOMES ASSESSMENTS

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OBJECTIVES: The objective of this study was to test cognitive debriefing strategies for translated Clinical Outcomes Assessments (COA) intended for pediatric populations. **METHODS:** Two questionnaires were translated into 11 languages, each for a specific pediatric population. One was an assessment on the palatability of medication, intended for ages 6-12. It was hypothesized that probe questions would be more effective for cognitive debriefing subjects aged 6-12. Subjects were asked how they would respond to the questionnaire in hypothetical conditions to demonstrate comprehensibility of the translated text. The second questionnaire contained visual analog scales (VAS) to assess pain for those aged 13-18. It was hypothesized that paraphrasing without supplementary probes, as used for adult subjects, would sufficiently determine comprehensibility for this age group. **RESULTS:** The palatability assessment was debriefed on 55 subjects with an average age of 9, and a standard deviation of 1.9. According to the results, the subjects showed probes were deemed to be a success with the younger sample, as they demonstrated their ability to understand how to respond to the questionnaire. The pain VAS scales were debriefed on 50 subjects with an average age of 15 and a standard deviation of 1.4. Results indicated that probes were not necessary if the nature of the questionnaire did not warrant them for subjects of any age. Paraphrasing definitively demonstrated comprehension by subjects aged 13-18. **CONCLUSIONS:** The results of cognitive debriefing data in this study show that probing is a viable method for cognitive debriefing of translated COAs with subjects aged 6-12 years old. For questionnaires intended for a population for 13-18 years of age, paraphrasing should sufficiently determine comprehension, as was demonstrated in this study, the same method that is used for adult subjects.

PRM115

USE OF WORK PRODUCTIVITY ENDPOINTS IN CLINICAL STUDIES: A REVIEW BY DISEASE STATE AND MEASUREMENT TYPE

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OBJECTIVES: Productivity outcomes are of interest because they describe the consequence of disease in the workplace and impact on productivity. We conducted an analysis of work productivity (WP) endpoints in clinical studies. **METHODS:** A keyword search was conducted on Clinicaltrials.gov for "work productivity" to identify relevant studies. Trials with terminated, withdrawn, or suspended status, those with non-drug interventions, and those without WP endpoints were excluded from analysis. A total of 170 studies were included (113 interventional and 57 observational studies). **RESULTS:** Of the 170 studies included, 44% were performed outside of the US, 31% were multinational studies including the US, and 25% were conducted exclusively in the US. The most common therapeutic categories investigated were autoimmune diseases (37%), neurology (14%), and psychiatry (9%). Most studies (84%) were sponsored by pharmaceutical manufacturers, with 11% sponsored by other institutions, or a combination of both (6%). The majority of trials investigated WP as a secondary measure (89%), with several, primarily observational studies, reporting WP as a primary outcome (11%). Survey instruments were utilized most commonly, representing 82% of studies, while 9% of studies evaluated WP based on time missed from work. Some studies utilized multiple measures. Generic instruments, such as the Work Productivity and Activity Impairment Questionnaire (WPAI), were used in 54% of studies, while 29% used disease-specific measures. In some cases (15%) a specific tool or instrument for WP was not identified. Most trials (93%) included other patient-reported endpoints, in addition to WP. **CONCLUSIONS:** WP endpoints were most commonly investigated in manufacturer-sponsored trials as secondary outcomes to demonstrate patient benefit in therapeutic areas where more concrete clinical outcomes are limited. Generic instruments are heavily utilized, with approximately one-third of studies utilizing disease specific measures.

PRM116

REVIEW OF CAREGIVER BURDEN SCALES FOR PATIENTS WITH VISUAL IMPAIREMENT IN JAPAN

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OBJECTIVES: Among the societal costs of visual impairment in Japan, cost of both unpaid and paid home care for people with visual impairment has been estimated as a substantial component of indirect cost. However, the degree of burden among individuals caring for visually impaired patients remains unknown. The study objective is to outlook the instruments currently available for measuring caregiver burden for visually impaired patients and to identify whether linguistic validation has been done in Japan. **METHODS:** We performed a literature review on articles describing instruments of caregiver reported outcomes for eye disorders. We summarized the current evidence on the usefulness of the instruments and whether they differentiate between eye diseases and other non-eye related diseases. In addition, we investigated possible hurdles in measuring caregiver burden in eye disorders, given the environmental understandings of patients with visual impairments and their caregivers in Japan. **RESULTS:** We identified two caregiver burden measurements, one depression measurement, and one life-satisfaction scale used in studies for measuring caregiver outcome for patients with visual impairments. A few studies using these instruments demonstrated correlation between the degree of caregiver burden and/or level of depression and severity of visual impairments. Excluding one caregiver burden instrument, Japanese versions of the remaining three instruments have been developed and validated. However, realistic use of these instruments are still questionable because: 1) most of the patients with visual impairments in Japan are elderly and increased caregiver burden may be due to conditions associated with older age, and 2) aging of caregivers are also progressing, resulting in increased perceived caregiver burden to support the patients. **CONCLUSIONS:** Evidence is limited when measuring the impacts of eye diseases on their caregivers. Further research is required to identify the usefulness of these instruments to measure caregiver burden for patients with eye diseases in Japan.

PRM117

DEVELOPMENT OF ELECTRONIC DIARY IN PATIENTS WITH PRIMARY BILIARY CIRRHOSIS

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OBJECTIVES: Primary biliary cirrhosis (PBC) is a disease with chronic symptoms such as fatigue and itching. To characterize the varied symptoms of PBC and evaluate benefits of new PBC treatments, an electronic diary (e-diary) was developed. **METHODS:** E-diary items were developed based on PBC-40 (health related questionnaire developed for PBC), other pruritis questionnaires and clinical consult. Concept elicitation interviews were conducted with PBC patients from the UK to further confirm PBC symptoms, symptom characteristics, impact and relevance. PBC patients with ongoing or previous (<2 years) symptoms participated. Cognitive debriefing of the diary was conducted with the e-diary format and confirmed usability. In addition, the interview evaluated the PBC-40 as 4 week recall period to determine feasibility of 1 week recall. **RESULTS:** 10 PBC subjects participated mean age 54.1, +12.9 years; 9/10 subjects were women. Subjects commonly reported experiencing itch, fatigue, and impacts on sleep, confirming importance for inclusion in the e-diary. Frequency of itch and fatigue also varied, supporting frequent capture. Subjects reported e-diaries were relevant, appropriate and could be easily used for symptom reporting. Interviews focusing on PBC-40 recall period supported the change from "past 4 weeks" to "past 1 week." **CONCLUSIONS:** Capture of PBC symptoms such as itch and other symptoms of PBC that vary frequently in an e-diary, and usability of the e-diary, was supported through interviews with PBC patients. Symptom characterization of itching could be further refined. Funding for this study was provided by GlaxoSmithKline

PRM118

ASSESSMENT OF TREATMENT ADHERENCE AND QUALITY OF LIFE IN DIABETIC PATIENTS TREATED WITH INSULIN IN TWO COLOMBIAN CITIES

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OBJECTIVES: Diabetes mellitus is a public health problem and its influence is recognized in the quality of life of patients. According to WHO, only 50% of people have adherence to treatment of chronic diseases. This study evaluated and compared the results of the scales measuring quality of life and adherence to treatment in two groups of patients with diabetes and treatment with conventional or analogue insulins **METHODS:** Cross-sectional study in two groups of patients diagnosed with diabetes mellitus type 1 or type 2, in medical treatment with conventional or analogues insulines, for at least six months in two cities in Colombia. The sample was calculated with a ratio of 0.5-Control Group, with estimated RR of 0.75 and allocation rate between groups of 0.5. Each patient responded two scales measuring quality of life (EQ-5D and Diabetes-39) and two scales measuring adherence (Morisky Green and Medication Possession Ratio) and comparison was made between the results obtained. **RESULTS:** 240 patients with a mean age of 57.7 ± 16.6 years were included, 69.6% were prescribed whit conventional insulin and 30.4% with analogues insulin. 68.3% of patients were adherent to medical therapy and only 7.1% (n = 17) had high quality of life. Patients more than 60 years were less likely to have high quality of life (OR: 0.177; 95% CI 0.050 to 0.635; p = 0.003), while adherence was less likely in patients aged 31-45 years (OR: 0.427; 95% CI 0.187 to 0.971; p = 0.038). **CONCLUSIONS:** The quality of life and treatment adherence is significantly affected in patients with diabetes mellitus, which may also impact its metabolic control. It is necessary to establish individual and group interventions to improve these conditions in patients.

PRM119

IMPORTANCE OF THE CONCEPTUAL DEFINITION OF PRO MEASURES: A CASE STUDY WITH THE LINGUISTIC VALIDATION OF THE IRRITABLE BOWEL SYNDROME QUALITY OF LIFE (IBS-QOL) INSTRUMENT IN 17 ASIATIC LANGUAGES

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OBJECTIVES: The Irritable Bowel Syndrome Quality of Life Instrument (IBS-QOL) is a self-report measure developed to assess the impact of IBS and its treatment. The instrument contains 34 items, rated on a five-point scale. The IBS-QOL was